K014162

510(k) Summary

JAN 15 2002

Submitted by: Daniel J. Manelli
Manelli, Denison & Selter, P.L.L.C.
2000 M Street, NW (Suite 700)
Washington, DC 20036

202-261-1000

On behalf of Lobob Laboratories, Inc.

510(k) Submission: Optimum™ Cleaning, Disinfecting and Storage Solution

January 10, 2002

Optimum Cleaning, Disinfecting and Storage Solution is intended to clean, disinfect and store fluorosilicone acrylate and silicone acrylate rigid gas permeable (RGP) and hard contact lenses. The product is a sterile solution containing lauryl sulfate salt of imidazoline, octylphenoxy polyethoxyethanol and preserved with benzyl alcohol.

The product is substantially equivalent to the currently marketed Lobob Optimum™ Cleaning, Disinfecting and Storage Solution (K001964). The product formulation, solubility, cleaning effectiveness and disinfection properties are similar to the predicate product. Labeling and indications for use are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2002

Lobob Laboratories, Inc.
c/o Mr. Daniel J. Manelli
Manelli Denison & Selter PLLC
2000 M Street, N.W. 7th Floor
Washington, D.C. 20036-3307

Re: K014162
Trade/Device Name: Optimum Cleaning, Disinfecting and Storage Solution
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC; HPX
Dated: December 19, 2001
Received: December 19, 2001

Dear Mr. Manelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Exhibit D

510(k) Number (if known): K014162

Device Name: Lobob Optimum Cleaning, Disinfecting and Storage Solution

Indications For Use:

To clean, disinfect and store fluorosilicone acrylate and silicone acrylate rigid gas permeable (RGP) and hard contact lenses

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K014162

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)